CV 12 5032

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK



UNITED STATES OF AMERICA,

Plaintiff,

v.

VENUS PHARMACEUTICALS INTERNATIONAL, INC., a corporation, and BHARAT KAKUMANU, an individual,

Defendants.

CIVIL ACTION NO. SPATT, J.

WALL, M.J.



# CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint For Permanent Injunction ("Complaint") against Venus Pharmaceuticals International, Inc., a corporation, and Bharat Kakumanu, an individual (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (the "Act").

3. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of food (dietary supplements as defined by 21 U.S.C. § 321(ff)) that are adulterated

within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, and held under conditions that do not conform to the current good manufacturing practice ("cGMP") regulations for dietary supplements set forth at 21 C.F.R. Part 111.

4. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration, within the meaning of 21 U.S.C. § 342(g)(1), of articles of food (dietary supplements), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

5. Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them, who receive actual notice of this Decree, are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a), and the equitable authority of this Court, from directly or indirectly manufacturing, preparing, processing, packing, labeling, holding, and/or distributing any dietary supplements, at or from 55-A Kennedy Drive, Hauppauge, New York 11788 ("the facility"), or at or from any other locations at which Defendants now, or in the future, directly or indirectly manufacture, prepare, process, pack, label, hold, and/or distribute dietary supplements, unless and until:

A. Defendants' methods, facilities, processes, and controls used to manufacture, prepare, process, pack, label, hold, and distribute dietary supplements are established, operated, and administered in compliance with this Decree, the Act, and its implementing regulations.

B. Defendants retain, at their expense, an independent person or persons (the "Expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants or their families, and who, by reason of background, training, education, or experience, is qualified to inspect the facility to determine whether the facility and the methods, processes, and controls that Defendants use to manufacture, prepare, process, pack, label, hold,

and distribute dietary supplements are operated and administered in conformity with cGMP, 21 C.F.R. Part 111. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity and qualifications of the Expert within five (5) calendar days of retaining such Expert;

C. The Expert performs a comprehensive inspection of the facility and the methods, processes, and controls that Defendants use to manufacture, prepare, process, pack, label, hold, and distribute dietary supplements and the labeling for all of Defendants' dietary supplements to determine whether Defendants are in compliance with 21 U.S.C. § 342(g)(1), 21 C.F.R. Part 111, and this Decree;

D. The Expert certifies in writing to FDA that:

i. The Expert has inspected the facility and the methods, processes, and controls that Defendants use to manufacture, prepare, process, pack, label, hold, and distribute dietary supplements;

ii. All cGMP deviations brought to Defendants' attention by FDA, the Expert, or any other source have been corrected; and

iii. The facility, methods, processes, and controls that Defendants use to manufacture, prepare, process, pack, label, hold, and distribute dietary supplements are in compliance with this Decree, the Act, and 21 C.F.R. Part 111. As part of the Expert's certification, a full and complete detailed report of the results of the Expert's inspection shall be provided by the Expert to FDA;

E. Defendants report to FDA in writing the actions they have taken to:

i. Correct all deviations brought to Defendants' attention by FDA, the Expert, and/or any other source; and

ii. Ensure that the methods and processes used in, and the facility and controls used for, manufacturing, preparing, processing, packing, labeling, holding, and distributing dietary supplements are operated, and will be continuously administered in conformity with cGMP, 21 C.F.R. Part 111;

F. Defendants' Expert, after review of all FDA observations from August 2010 to present, develops and submits to FDA for approval a written product sampling and testing plan that shall apply to all dietary supplements manufactured, prepared, processed, packed, labeled, held, and/or distributed during the time period beginning June 25, 2010, through and including January 20, 2012, which shall include, at a minimum, the following:

i. A description of the reserve samples of batches to be tested. If Defendant does not have the reserve samples required by 21 C.F.R. § 111.83(a), Defendant shall recall from customers sufficient samples to conduct adequate testing for each batch;

ii. A product sampling and testing program that establishes adequate methods and controls for testing already released product. Such methods and controls shall include, but shall not be limited to:

a. Testing for heavy metal and elemental contaminants (ICP-MS);

b. Testing for microbial, yeast, and mold including total plate counts and speciation as appropriate;

c. Pesticide residue analysis;

d. Active Pharmaceutical Ingredient analysis for those products with intended uses for bodybuilding, sexual enhancement, and/or weight-loss; and

e. Other known contaminants that would adulterate the product;

iii. The name of an accredited laboratory facility where the proposed testing will take place.

G. FDA approves, in writing, the product sampling and testing discussed in paragraph 5(F) above;

H. The Expert shall ensure product testing, in accordance with paragraph 5(F) above. The Expert shall submit all findings to Defendants and FDA concurrently, so that FDA may determine whether to order a recall based on the results of the testing;

I. FDA notifies Defendants, in writing, the results of the recall determination conducted under 5(H) above;

J. Defendants fully complete the appropriate recall ordered under 5(I) above, if any, and destroy the recalled dietary supplements under FDA's supervision and in accordance with paragraph 9 below;

K. In the alternative to the testing outlined in paragraphs 5(F)-5(J), Defendants may recall and destroy, under FDA's supervision and in accordance with the procedures provided in paragraph 9, all dietary supplements that were manufactured, prepared, processed, packed, labeled, held, and/or distributed during the time period beginning June 25, 2010, through and including January 20, 2012.

L. FDA, as and when it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and applicable regulations, conducts inspections of the facility, including the buildings, equipment, utensils, dietary supplements, labeling, and all relevant records contained therein;

M. Defendants have paid all cost of supervision, inspections, investigations, analyses, examinations, and reviews for FDA's oversight with respect to paragraph 5, at the rates set forth in paragraph 13 below; and

N. FDA has notified Defendants, in writing, that Defendants appear to be in compliance with all the requirements specified in subparagraphs 5(A)-(F), (H), (J), (K) and (M) of this Decree, the Act, including 21 U.S.C. § 342(g)(1) and all applicable regulations, including 21 C.F.R. Part 111. In no circumstance shall FDA's silence be construed as a substitute for written notification.

6. Notwithstanding Defendants' intent to resume operations, Defendants shall comply with paragraphs 5(B) and 5(F)-5(J) or with paragraph 5(K) above. Defendants' submission under paragraph 5(F) shall be received by FDA no later than twenty-one (21) days after entry of this Decree.

7. The terms of paragraph 5 shall not prohibit Defendants from manufacturing, preparing, processing, packing, labeling, holding, and/or distributing a dietary supplement that was never sold or offered for sale in domestic commerce and that is intended solely for export from the United States, provided that any such dietary supplement complies with all of the requirements of 21 U.S.C. § 381(e)(1) and 21 C.F.R. § 1.101.

8. Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any all persons or entities in active concert or participation with any of them, who have received actual notice of this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

A. violates the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into interstate commerce, of any dietary supplement, within the meaning of 21 U.S.C. § 321(ff), that is adulterated within the meaning of 21 U.S.C. § 342(g)(1);

B. violates the Act, 21 U.S.C. § 331(k), by causing any dietary supplement within the meaning of 21 U.S.C. § 321(ff) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such dietary supplement is held for sale after shipment of one or more of its components in interstate commerce; and/or

C. results in the failure to implement and continuously maintain the requirements of this Decree.

9. Within fifteen (15) calendar days of entry of this Decree and within ten (10) calendar days after receiving any recalled dietary supplements, Defendants shall, under FDA supervision, destroy all dietary supplements in Defendants' possession, custody, and/or control because they are adulterated in that they were not manufactured, prepared, packed, labeled, held and/or distributed in accordance with cGMP, 21 C.F.R. Part 111. Defendants shall reimburse FDA for supervising the destruction at the rates set forth in paragraph 13 of this Decree. Defendants shall not dispose of any dietary supplements in a manner contrary to any federal, state, or local laws.

10. After Defendants have complied with paragraphs 5(A)-(F), (H), (J), (K) and (M), and FDA has notified them pursuant to paragraph 5(N), Defendants shall retain an independent person or persons who shall meet the criteria described in paragraph 5(B) to conduct audit inspections of their dietary supplement manufacturing operations (hereinafter, the "Auditor") at least once every three (3) months, for a period of no less than two (2) years, then at least once

every six (6) months thereafter. If Defendants choose, the Auditor may be the same person or persons retained as the Expert in paragraph 5(B).

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written report ("audit report") analyzing whether Defendants are in compliance with this Decree, the Act, and its implementing regulations, and identifying any deviations ("audit report observations"). As part of every audit report, except the first audit report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than ten (10) business days after the date the audit inspection(s) is completed. In addition, Defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any observations indicating that Defendants are not in compliance with this Decree, the Act, and/or its implementing regulations, Defendants shall, within fifteen (15) calendar days after receiving the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that a correction of the deviations will take longer than fifteen (15) calendar days, Defendants shall, within five (5) calendar days after receiving the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule"). The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days after Defendants receive an audit

report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time frame provided in a correction schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days after beginning that review, the Auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

11. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' operations, and without prior notice, to take any other measures necessary to monitor and ensure continuous compliance with the terms of this Decree, the Act, and all applicable regulations. During such inspections, FDA representatives shall be permitted: immediate access to Defendants' places of business including, but not limited to, all buildings, equipment, finished and unfinished materials and products, containers, labeling, and other material therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, labeling, packaging material, and other material; and to examine and copy all records relating to the receiving, manufacturing, preparing, processing, packing, labeling, holding, and distribution of any and all of Defendants' dietary supplements, including components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

12. Defendants shall promptly provide any information or records to FDA upon request regarding the receiving, manufacturing, preparing, processing, packing, labeling, holding, and distribution of dietary supplements.

13. Defendants shall reimburse FDA for the costs of all FDA inspection, investigations, supervision, analyses, examinations, sampling, testing, reviews, and document preparation that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree. The costs of such activities shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred, and Defendants shall make payment in full to FDA within thirty (30) calendar days of receiving written notification from FDA of the costs. As of the date this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per representative for inspection or investigative work; $104.96 per hour and fraction thereof per representative for analytical or review work; $0.55 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further Order of the Court.

14. Within ten (10) calendar days after entry of this Decree, Defendants shall post a copy of this Decree in a conspicuous location in a common area at the facility and at any other location(s) at which Defendants manufacture, prepare, process, pack, label, hold, and/or distribute dietary supplements, and shall ensure that the Decree remains posted at each location for as long as the Decree remains in effect. Within fifteen (15) calendar days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with this paragraph.

15. Within ten (10) calendar days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all employees, at which they shall describe the terms and obligations of this Decree. Within fifteen (15) calendar days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with this paragraph, and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

16. Within fifteen (15) calendar days after entry of this Decree, Defendants shall provide a copy of the Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of Defendants' directors, officers, agents, employees, representatives, attorneys, successors, assigns, parties for whom Defendants contractually manufacture dietary supplements, and any and all persons or entities in active concert or participation with any of them (collectively referred to as "Associated Persons"). Within thirty (30) calendar days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with this paragraph and identifying the names, addresses, and positions of all persons who received a copy of this Decree pursuant to this paragraph.

17. In the event that any Defendant becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested) to such Associated Person(s). Within ten (10) calendar days of each time that any Defendant becomes associated with any additional Associated Person, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and

manner of Defendants' compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) calendar days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

18. Defendants shall notify FDA, in writing, at least fifteen (15) calendar days before any change in ownership, character, or name of their business, including reorganization, relocation, dissolution, bankruptcy, assignment, sale resulting in the emergence of a successor business or corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure or identity of Venus Pharmaceuticals International, Inc., or any of their parents or subsidiaries, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least ten (10) calendar days prior to any sale or assignment. Defendants shall furnish FDA an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

19. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample(s), a report or data prepared or submitted by Defendants, the Expert, the Auditor, or any other information, that, at the facility or any other locations at which Defendants, now or in the future, directly or indirectly, manufacture, prepare, process, pack, label, hold, and/or distribute dietary supplements, Defendants have failed to comply with any provision of this Decree, have violated the Act or applicable regulations, or that additional

corrective actions are necessary to achieve compliance with this Decree, the Act, and/or applicable regulations, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate action, including, but not limited to, ordering Defendants immediately to take one or more of the following actions:

A. Cease manufacturing, preparing, processing, packing, labeling, holding and/or distributing any or all dietary supplement(s);

B. Recall, at Defendants' own expense, any dietary supplement that is adulterated, misbranded, or otherwise in violation of this Decree, the Act, and/or its implementing regulations;

C. Revise, modify, or expand any reports, plans, procedures, and/or other records prepared pursuant to this Decree;

D. Submit additional reports or information to FDA;

E. Institute or reimplement any of the requirements set forth in this Decree;

F. Issue a safety alert; and/or

G. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health and/or to bring Defendants into compliance with this Decree, the Act, and/or its implementing regulations.

Defendants shall pay all cost of recalls and other corrective actions, including the costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor recalls and other corrective actions, at the rates specified in paragraph 13. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

20. Upon receipt of any order issued by FDA pursuant to paragraph 19, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other actions described in paragraph 19 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations.

21. If any Defendant fails to comply with any of the provisions of this Decree, the Act, and/or applicable regulations, then Defendants shall pay to the United States of America the sum of ten thousand dollars ($10,000) in liquidated damages for each day such violation continues and an additional sum of ten thousand dollars ($10,000) in liquidated damages for each violation of this Decree, the Act, and/or applicable regulations (e.g., if two violations occur for two business days, the liquidated damages shall be $40,000), and an additional sum equal to twice the retail value of each shipment of adulterated dietary supplements in liquidated damages for each such unlawful shipment. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the Court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

22. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to the contempt proceedings.

23. All decisions specified in this Decree shall be vested in the discretion of the FDA. FDA's decisions shall be final and, to the extent these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

24. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be addressed to the Director, FDA New York District Office, 158-15 Liberty Avenue, Jamaica, New York 11433, and shall reference this civil action by case name and civil action number.

25. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

Case closed

SO ORDERED:

UNITED STATES DISTRICT JUDGE

Dated this 15th day of OCTOBER, 2012

We hereby consent to the entry of this Decree:

For Defendants:

BHARAT KAKUMANU,
on behalf of
Venus Pharmaceuticals International, Inc.

BHARAT KAKUMANU,
in his individual capacity

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